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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,193	09/29/2005	Genevieve Andre-Fontaine	033339/292053	9098

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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02/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,193	Applicant(s) ANDRE-FONTAINE ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,21,22 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,21 and 22 is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 6, 2009 has been entered.
2. Claims 6 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claims 6 and 29 are improper dependent claims, because there is no language or limitation in the independent claim which embraces coupling of a carrier protein to the peptide of SEQ ID NO:1 (or to the peptide with the N-terminal cysteine residue), or which embraces forming salts of the peptide of SEQ ID NO:1 (or to the peptide with the N-terminal cysteine residue). In view of the "consists of" language used to define the compound of independent claim 1, salts of the peptides and further covalent modification of the peptides are excluded from the scope of the independent claim. Dependent claims 6 and 29 recite compounds which are not embraced within the scope of the independent claim, i.e. it is possible to infringe dependent claims 6 and 29 without infringing independent claim 1, and therefore claims 6 and 29 are improper dependent claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/59123. (The examiner relies upon U.S. Patent Application Publication

2003/0124567 as a translation of the WO Patent Application '123. All citations in this rejection will be to the text of the translation.) The WO Patent Application '123 teaches a PPL protein of 32 kDa and comprising SEQ ID NO:7, whose residues at positions 153-177 are 100% similar to Applicants' SEQ ID NO:1. The WO Patent Application '123 also teaches immunogenic compositions comprising the protein, and the protein immobilized on solid supports. See, e.g., paragraphs [0024], [0067], [0070], [0086], and [0089], and claims 3 and 29 of the translation. The fragments at residues 1-152 and 178-280 of the PPL protein of the WO Patent Application '123 correspond to Applicants' carrier protein. Applicants' claim does not contain any restrictions on the term "carrier protein" which act to exclude full-length PPL from its scope. Further, process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

5. Applicant's arguments filed January 6, 2009 have been fully considered but they are not persuasive.

The objection to claims 6 and 29 under 37 CFR 1.75(c) is maintained. It is not relevant as to whether the peptide coupled to a carrier protein of claim 6, or the salt form of the peptide of claim 29, are narrower in scope than the peptides recited in independent claim 1. Rather, the issue under 37 CFR 1.75(c) is whether or not the products of dependent claims 6 and 29 are embraced within the scope of the independent claim, i.e. whether or not it is possible to infringe the dependent claims without infringing the independent claims. See also MPEP 608.01(n)(II) and (III). Because the "consists of" language present in the independent claim excludes any further modification of the two peptides, salt forms of the two peptides are not encompassed by the independent claim, and modification of the two peptides with carrier proteins are not

encompassed by the independent claim. With respect to dependent claim 29, this objection could be overcome by re-introducing the “pharmaceutically acceptable salts of said peptide” language into the independent claim.

The rejection of claim 6 under 35 U.S.C. 102(b) based upon the WO Patent Application 01/59123 is maintained. Applicants contend that it is not possible to form full length PPL protein by either of the methods recited in claim 6. The examiner does not agree. Full length PPL can be synthesized, e.g., by chemically coupling a peptide corresponding to residues 153-177 of PPL with a peptide corresponding to residues 178-280 of PPL, and then chemically coupling the resulting peptide with a peptide corresponding to residues 1-152 of PPL. Full length PPL can be synthesized, e.g., by adding a DNA coding sequence for residues 1-152 of PPL to a DNA coding sequence for residues 153-177 of PPL, and then adding the resulting DNA coding sequence to a DNA coding sequence for residues 178-280 of PPL, and then expressing the resulting DNA coding sequence as a fusion protein. Claim 6 contains no language which excludes full length PPL from its scope.

6. Claims 1, 21, and 22 are allowed. Claim 29 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal

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communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
February 24, 2009